

Serial No. 10/800,992
Docket No: D-2804CON2

REMARKS

Applicants are in receipt of the Office Action mailed January 4, 2006, and have the following comments.

Rejection pursuant to 35 USC §102(b)

The Examiner has again rejected claims 31-36, 39-46 and 49-50 as allegedly anticipated over Loftsson et al., U.S. Patent. No. 5472,954. Applicants respectfully traverse this rejection for the following reasons.

A claim is not anticipated unless a single prior art reference contains each and every limitation of the claim and teaches a person of skill in the art to make and use the invention without undue experimentation. See e.g., *In re Paulsen*, 31 USPQ 2d 1671 (Fed. Cir 1994).

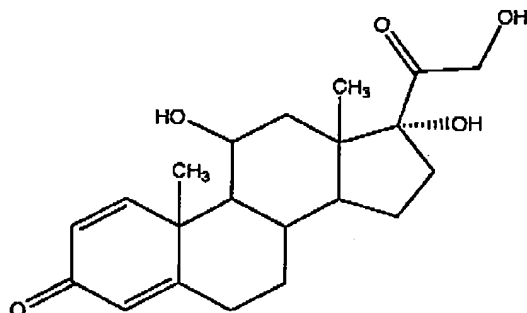
MPEP 2131.01 (II) (Rev. 3, August 2005) states that an extra reference can be used "to explain the meaning of a term used in the primary reference."

The January 4 Office Action does not dispute that Loftsson does not mention or discuss prednisolone acetate, a necessary element of all the pending claims.

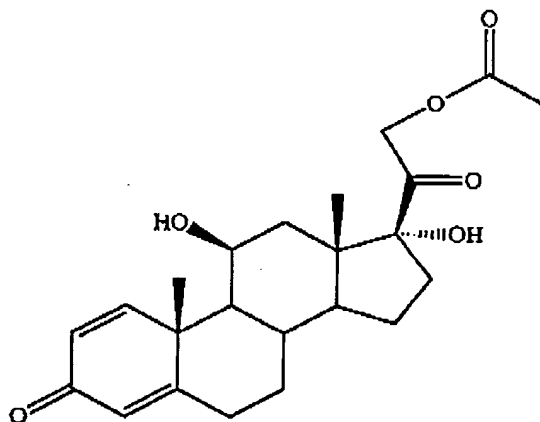
In an attempt to show that the term "prednisilone", which appears in the cited Loftsson reference, is synonymous with "prednisolone acetate" the January 4, 2006 Office Action has cited the Merck Index 11th ed. pages 1223-1224 (1989). That is, the Office Action asserts that one of skill in the art would necessarily understand that the term "prednisolone" used in the primary reference actually means "prednisolone acetate", in a manner such that Loftsson inherently discloses prednisolone acetate by expressly disclosing prednisolone.

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With respect, Applicants submit that the 11th edition of the Merck Index supports exactly the opposite proposition. Under Monograph 7719, the formula for prednisolone is given as follows:



By contrast, the formula for prednisolone acetate (prednisolone-17-acetate), as discussed in the October 3rd Reply, is:



That these are different compounds is attested to by the fact that prednisolone has a different chemical structure than prednisolone acetate. Moreover, these two compounds have different molecular weights (358.44 versus 402.48, respectively), distinct and different names, and different chemical properties, as listed in the Monograph.

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Additionally, Monograph 7807 in the 13th edition of the Merck Index (2001) (relevant pages of which are hereby submitted herewith in a Form 1449) makes it clear that the 21-acetate derivative of prednisolone, like the other 6 compounds listed in bold under Monograph 7807, are indeed derivatives of (rather than "synonymous with") the title compound. All these compounds have distinct chemical and/or physical properties, as listed under this entry.

Synonyms of prednisolone are listed in regular (i.e., unbolded) font directly following the Chemical Abstracts Registry Number (see 13th edition Merck Index at ix and Monograph 7807). Synonyms of prednisolone include a number of trade names for pharmaceutical products. If the term "prednisolone" were generally understood to mean "prednisolone acetate", then the buyers of these products (medical patients) would be confused, as they would be receiving the free base rather than prednisolone-17-acetate that they would understand the products to contain. Clearly then, these two compounds are generally considered to be distinct by the person of ordinary skill in the art, and would be so understood by regulatory agencies such as the U.S. Food and Drug Administration in order to protect patient health and safety. In other words, labeling a pharmaceutical product containing prednisolone-17-acetate as "prednisolone" would clearly violate drug-labeling requirements.

Finally, the 13th edition of the Merck Index makes clear that prednisolone has a Chemical Abstracts Registry Number of [50-24-8], while prednisolone-17-acetate has a Chemical Abstracts Registry Number of [52-21-1]. See page ix and Monograph 7807. Clearly those of skill in the art consider these two compounds to be different and not synonymous. A copy of these pages of the 13th edition of the Merck Index is provided herein for the Examiner's convenience.

For these reasons, Applicants maintain their position that Loftsson does not anticipate the present claims, incorporate by reference the arguments made in the October 6th Reply, and request the Examiner to

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reconsider and withdraw the rejection pursuant to 35 U.S.C. 102(b) over Loftsson.

Rejection pursuant to 35 USC §103(a)

The Examiner has maintained the rejection of claims 31, 36-38 and 46-48 as allegedly obvious over Loftsson, and claims 37-38 as allegedly obvious over Loftsson further in light of Dziabo et al., U.S. Patent No. 5,424,078. The Examiner alleges that Loftsson et al. teaches a preserved cyclodextrin and prednisolone ophthalmic composition, and that Dziabo et al. disclose chlorite as a preservative. Applicants respectfully traverse this rejection for the following reasons.

As discussed above, the Loftsson reference does not disclose an ophthalmic composition containing the compound being claimed in the present claims, prednisolone acetate. This fact is supported by the 13th edition of the Merck Index, page ix and Monograph 7807, which have been made of record herein.

The Manual of Patent Examining Procedure (MPEP), relying on long-established judicial precedent, states that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so in the references or otherwise within the knowledge of the person of ordinary skill in the art. See MPEP § 2143.01. There is nothing in Loftsson et al., or in the combination of Loftsson and Dziabo et al., that would suggest the specifically claimed compositions containing prednisolone acetate, a compound not even mentioned in either reference, or methods of using such compositions. For this reason, the Applicants respectfully request the Examiner to withdraw this rejection and permit the present claims to proceed to issue.

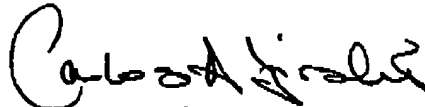
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Applicants further incorporate by reference the arguments made in the October 6th Reply.

CONCLUSION

For the above reasons Applicants submit that the claims here in condition for allowance and respectfully request that the Examiner issue a notice to that effect.

Respectfully submitted,



Carlos A. Fisher
Attorney for Applicant
Reg. No. 36, 510
4 Venture, Suite 300
Irvine, CA 92618
(949) 450-1750
Facsimile (494) 450-1764